

**REMARKS**

Claims 1-22 are all the claims pending in the application; claims 9 and 10 have been withdrawn from consideration; claims 1-8 and 11-22 are rejected.

Claims 8 and 22 have been amended to correct the improper dependency noted by the Examiner in the outstanding office action. Specifically, claim 8 has been amended to incorporate the subject matter of claim 1, and to depend solely from claim 7. Similarly, claim 22 has been amended to incorporate the subject matter of claim 2, and to depend solely from claim 7.

No new matter has been added. Entry of the amendment is respectfully requested.

**I. Claims Objections**

At paragraph 4 of the Office Action, claims 8 and 22 are objected to under 37 C.F.R. §1.75(c) as being in improper form. The Examiner states that claim 8 should depend from claim 1 or claim 7, but not from both. A similar objection is made to claim 22.

In response, Applicants include herewith amendments to claims 8 and 22. Claim 8 has been amended to incorporate the subject matter of claim 1, and to depend solely from claim 7. Similarly, claim 22 has been amended to incorporate the subject matter of claim 2, and to depend solely from claim 7.

In view of the amendments to the claims, Applicants respectfully request reconsideration and withdrawal of this objection.

**II. Rejection of Claims Under 35 U.S.C. §§101 and 112**

A. At paragraph 3 of the Office Action, claims 1-8 remain rejected and new claims 11-22 are rejected under 35 U.S.C. §101 as lacking a patentable utility.

The Examiner states that the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons of record in the previous Office Action (dated September 24, 2001) at pages 3-6.

In response to Applicants' arguments in the Amendment dated March 25, 2002, the Examiner states that Applicants have provided convincing evidence that the polypeptides of the present invention are members of the TNFR family.

The Examiner goes on to discuss the Eby et al. reference and states that the TAJ protein disclosed therein is a likely splice variant of SEQ ID NO: 4 of the present invention. Indeed, the Examiner recognizes that TAJ is equivalent to SEQ ID NO:4 of the present invention (encoding OAF065 $\alpha$ ) at page 5, lines 3-4, of the office action.

The Examiner further states that while Eby et al. suggests a role for the proteins in TRAF-mediated signal transduction pathways and apoptosis, such functions are not present or envisioned in the specification as originally filed.

Applicants' comments

A review of Eby et al. shows that the TAJ protein disclosed therein has the ability to induce cell death (see, e.g., page 15340, column 2, fifth full paragraph, lines 2-3). Further experiments described therein suggest a novel mechanism for inducing cell death apart from caspase-induced apoptosis.

As discussed above, the Examiner has recognized that the TAJ protein and the protein of the present invention are substantially the same. Thus, the protein of the present invention has the same function and activity as the TAJ protein, namely, the ability to induce cell death.

The present specification discloses as one of the activities of the protein of the present invention the ability to induce cell death. For example, at page 17, lines 6-10, it is stated that the polypeptide of the present invention will show biological activities including cell death. More specifically, at pages 28-29 is a description of specific cell types in which the polypeptide of the present invention is expected to induce cell death, including cells of immune system and hematopoietic origin, and cells of the nervous system. In each case, the polypeptide of the present invention is said to be involved in "cell death."

Thus, it is clear that a specific and substantial asserted utility has been disclosed for the polypeptide of the present invention (the ability to induce cell death), and that the experimental results in Eby et al. strongly support that utility.

Applicants also note that in view of this specific and substantial asserted utility, and the importance of the appropriate control of cell death in the treatment of disease, the skilled artisan would readily understand that a polypeptide involved in the induction of cell death could be used in a number of important manners. For example, it could be used for preparing an agent for treating or diagnosing diseases caused by uncontrolled cell death, for screening for other factors related to cell death, and the like. A discussion of some roles for the polypeptide of the present invention in such important activities is provided at page 29, line 22, through page 30, line 8.

In view of the points discussed above, and the evidence for a specific and substantial asserted utility for the polypeptide of the present invention, Applicants respectfully request reconsideration and withdrawal of this rejection.

**B.** At paragraph 4 of the Office Action, claims 1-8 remain rejected and new claims 11-22 are rejected under 35 U.S.C. §112, first paragraph, as being non-enabled.

The Examiner asserts that because the claimed invention is allegedly not supported by either a specific and substantial asserted utility, or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Applicants' comments

In response, Applicants again assert that the claimed invention is supported by a specific and substantial asserted utility for the reasons discussed above.

Furthermore, the skilled artisan would clearly understand how to make and use the polypeptide of the present invention for the asserted utility without undue experimentation. The knowledge in the art and the expertise of an artisan working in the field of molecular biology is such that the skilled artisan would be able to use the claimed polypeptide for those uses discussed at page 29, line 22, through page 30, line 8, of the specification, without further specific instruction. One example would be in the induction of cell death in a population of cancer cells through the introduction into the population of an expression vector comprising the coding sequence of the polypeptide.

Given the specific and substantial asserted utility, and the knowledge of the skilled artisan, Applicants state that the present invention is adequately enabled and therefore respectfully request reconsideration and withdrawal of this rejection.

**III. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Drew Hissong  
Registration No. 44,765

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE



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PATENT TRADEMARK OFFICE

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**APPENDIX**  
**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

**The claims are amended as follows:**

8. (Twice amended) A method for producing a polypeptide that comprises the amino acid sequence shown in SEQ ID NO: 4 or 8, or that comprises an amino acid sequence having at least 95% homology with the amino acid sequence shown in SEQ ID NO: 4 or 8, the polypeptide according to claim 1 which comprises culturing a host cell according to claim 7 under conditions effective to express said the polypeptide according to claim 1, and recovering the polypeptide so expressed.

22. (Amended) A method for producing a polypeptide that comprises the amino acid sequence shown in SEQ ID NO: 4 or 8, the polypeptide according to claim 2, which comprises culturing a host cell according to claim 7 under a condition effective to express said the polypeptide according to claim 2, and recovering the polypeptide so expressed.